IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Bhullar et al.

Application No.: 09/704,235 Group No.: 1753

Filed: 01-Nov-00 Examiner: Noguerola, A.

For: Biosensor

I, Brian S. Hill, a named inventor of U.S. Application Serial No. 09/704,235, filed 09/704,235 hereby state the following:

In May 2004, I constructed twenty-nine (29) prototypes in accordance with the teachings of the above-identified application. Of those twenty-nine (29) prototypes, twenty-two (22) successfully transferred fluid through its channel in a timely manner and without leakage. The specific results are set out in Appendix A. A video file of Sample #1 was collected on a digital camera and is attached as Appendix B.

Details regarding the construction of the prototypes are as follows:

COMFORT CURVE® sensors, commercially available from Roche Diagnostics Corporation, Indianapolis, IN were disassembled.

A. A slit was made across the entire sensor, approximately 7 mm from the capillary end. The relevant architectural elements were the two layers of 7 mil (175 micron) MELINEX® 329 (commercially available from DuPont Teijin Films U.S. Limited Partnership, Hopewell, VA, sandwiching a 90 micron layer of hot melt bonding adhesive GRILTEX 1698 (RDO commercially available from EMS-Chime).

B. The top layer of each sensor, between the slit and the capillary end, was pressed gently against a Sunbeam 3040 household iron, commercially available from Sunbeam Products, Inc., Boca Raton, FL (temperature setting between polyester and cotton) and moved back and forth for approximately 20 seconds.

C. A fine forceps was used to carefully remove the top layer, consisting of the hydrophilic label and the top 7 ml MELINEX® foil) from the bottom layer (electrodes embedded in hot melt, reagent on bottom 7 mil MELINEX® substrate).

D. A clear top foil, comprised of 1 mil HY-10 hydrophilic hot melt solvent coated on 5 mil (125 micron) MELINEX® 453 (RDO commercially available from Adhesives Research) was cut to size and placed over the capillary end. The Sunbeam 3040 household iron was pressed firmly against this pre-laminate and moved gently over the region to be sealed for approximately 10 seconds.

All regions other than those immediately over the reagent were laminated in this way, by observing the HY-10 layer through the MELINEX®, the melting of the adhesive was observed.

E. After lamination, the new top foil was trimmed.

The test procedure was as follows:

A. Test fluid was a 3S Level 1 Linearity solution (lot 3SLB010804), produced internally by Centralized Diagnostics. Because the fluid layer was so thin, image contrast was improved by adding additional FD&C Blue Dye #1 to darken the liquid's blue color.

B. Sample sensors were mounted in a jig consisting of an ADVANTAGE® meter, commercially available from Roche Diagnostics Corporation, Indianapolis, IN and dosed from below.

C. Images were collected in a Casablanca digital imaging system; timing was performed with a Horita VS-50 digital stopwatch, which was coupled to the video system to provide a timebase index.

D. After dosing was completed, the fill times were determined by reviewing the digital video file; the start time was determined one or more frames prior to initial contact of the sample fluid and the top foil; the fill time was determined one or more frames after fluid reached the designated position.

REMARKS

Of twenty-nine (29) prototypes, twenty-two (22) successfully transferred fluid through their respective channel in a timely manner and without leakage. The specific results are set out in Appendix A. A video file of Sample #1 was collected on a digital camera and is attached as Appendix B. The video file is run on a Quick Time Player, commercially available from Microsoft Corporation, Seattle, WA.

In Appendix A, "Electrode coverage time" is the time to cover both the counter and working electrodes after first contact of fluid with the capillary entrance. "Sensor fill time" is the time for fluid to completely fill the capillary and/or cease flowing. The term "Leaker" indicates that the capillary channel was not fully sealed with the Sunbeam 3040 household iron.

It is noted that each of the leakage failures was due to faulty workmanship, given the limitations of the Sunbeam 3040 household iron. A hot melt laminate in production would probably use a heated die/roller (aligned with the preexisting reagent layer) thereby providing uniform heat and pressure for an optimized time over the desired sealing area. Due to time constraints, that option was not available to me. Because of that deficiency, I had a finite probability of not providing uniform bonding between the hot melt adhesive layers. In addition, due to immediate availability, I used hot melt layers that were optimized for other architectures, sensor formats, and assembly protocols.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like

so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: June 9, 2004 Signature:

Brian S. Hill

APPENDIX A

Sample #	Electrode Coverage Time (s)	Sensor Fill time (s)	Comments
1	0.40		
2	0.40	0.57	
3	0.28	0.54	
4	2.94	16.19	Capillary entrance & capillary largely sealed
5	0.44	0.80	Leaker
6	0.43	0.93	
7	0.56	0.70	
8	0.34	0.54	
9	0.34	0.50	
10	0.27	1.22	
11	0.37	0.77	Partial Capillary entrance blockage
12	0.53	0.97	
13	N/A		Capillary entrance sealed
14	0.40	1.13	
15	0.47	1.54	Leaker
16	0.34	4.14	Severe leaker
17	0.57	1.00	
18	0.27	0.57	Severe leaker
19	0.30	0.64	
20	16.95		Capillary entrance & capillary largely sealed
21	0.46	0.86	
22	0.37	0.83	
23	1.40	3.17	
24	0.37	0.64	
25	0.37	1.07	
26	0.53	0.95	
27	0.20	0.40	
28	0.40	0.67	
29	5.11		Capillary entrance & capillary largely sealed